REMARKS

Claims 1-21 are pending. By virtue of this response, claims 13, 17 and 18 are amended, and claim 12 is canceled. Therefore, claims 1-11 and 13-21 are presently under examination. Support for the amendments to claims 13, 17 and 18 may be found throughout the specification including, without limitation, on page 2, lines 4-27 and page 3, lines 6-12. Amendment and cancellation of certain claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented. No new matter is added.

I. Claim Rejections Under 35 USC §102

Claims 17 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Ho *et al.* Vaccine 19 (2001) 716-725.

Applicants respectfully traverse the rejection and its supporting remarks. Ho *et al.* clearly fails to anticipate the invention as there is no teaching of a computer apparatus of claim 17, wherein the computer apparatus comprises "a computer-readable storage medium storing computer-executable instructions for performing the process steps of any one of claims 1 to 12." Likewise, Ho *et al.* does not teach a computer-readable storage medium of claim 18, wherein the computer-readable storage medium comprises a "computer-executable instructions for analysing the saccharide content of a composition as defined in claim 1, comprising computer-executable instructions for: (a) receiving data on the sialic acid content, and on the glucose and/or galactose content, of a sample; and (b) calculating from those data the content of capsular saccharide from serogroup C and from serogroup W135 and/or Y."

Applicants therefore respectfully request that the Examiner withdraw the rejections of claims 17 and 18.

II. Claim Rejections Under 35 USC §103 – Ryall in view of Ho and Claus

Claims 1-11 and 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ryall *et al.* WO 02/058737 8/1/02, in view of Ho *et al.* Vaccine 19 (2001) 716-725 and Claus *et al.* Mol Gen Genet (1997) 257:28-34.

Applicants respectfully traverse the rejection and its supporting remarks. As discussed on page 2, lines 4-27 and elsewhere in the specification, the inventors have found a process for analyzing the saccharide content of the composition of claim 1, which comprises saccharides of least two or three different *Neisseria meningitidis* serogroups (serogroup C and one or both of serogroup W135 and serogroup Y). Such compositions may occur as part of a combination vaccine against *Neisseria meningitidis*. Accurate analysis of the saccharide content of the composition of claim 1 is important, for example, for assessing the saccharide content of a vaccine for quality control purposes.

As explained in the "Background Art" section of the specification, analysis of the saccharide content of the composition of claim 1 is not straightforward. At least two factors contribute to the difficulty in accurate analysis of the saccharide content of the composition of claim 1: 1) the methods typically used for saccharide analysis, and 2) the specific saccharides present in the composition of claim 1.

First, as explained in page 1, lines 27-34 of the specification, analysis of saccharide polymers is typically not performed on intact saccharide polymers. Instead, the saccharide polymers are first hydrolyzed into saccharide monomers, which are then analyzed.

Second, even though the composition of claim 1 comprises saccharides of least two or three different serogroups (serogroup C and one or both of serogroup W135 and serogroup Y), all of these saccharides are, at least in part, composed of the same monosaccharide, sialic acid. (Saccharides of serogroup C are composed of only sialic acid, while saccharides of serogroup W135 contain both sialic acid and the monosaccharide galactose, and saccharides of serogroup Y contain both sialic acid and the monosaccharide glucose.)

Thus, when a composition of claim 1 is prepared for saccharide analysis by hydrolyzing the saccharides into monomers, sialic acid monomers will be released from the saccharides of each of serogroup C, W135, and Y. As explained in page 1, lines 27-34 of the specification, this presents a problem for accurate determination of the amount of each different saccharide in the original composition, because in an analysis based on sialic content, it is unclear whether sialic monomers were released from saccharides of serogroup C, W135, or Y.

In view of this difficulty, claim 1 provides a process for analyzing the saccharide content of a composition of claim 1. The process of claim 1 includes the detailed steps of claim elements (b) – (e), which, taken together, provide steps for determining the amount of each of serogroup W135, Y, and C saccharides in a composition.

In contrast, none of the art identified by the Examiner teaches a process for analyzing the saccharide content of the composition of claim 1 (e.g. how to accurately determine the saccharide content of the composition, given that saccharides of serogroup W135, Y, and C all contain sialic acid). Nor does any of the art recognize the difficulties associated with analyzing the content of the composition of claim 1 as a problem needing to be solved.

The references fail to provide a teaching, suggestion, or motivation to arrive at the claimed invention

As indicated in MPEP Section 2141(II)(A)-(C), assessing obviousness is a three step procedure initially set out by the Supreme Court in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966):

> (A) Determine the Scope and Content of the Prior Art
>
> (B) Ascertain the Differences Between the Claimed Invention and the Prior Art
>
> (C) Resolve the Level of Ordinary Skill in the Art

Turning to the teachings of the references cited by the Examiner, Ho *et al.* analyzes a composition containing only serogroup C saccharide (which consists of only sialic acid) and thus it does not deal

with compositions having mixed saccharide content. Claus *et al.* mentions serogroups B, C, W135, and Y, but does not provide any actual saccharide analysis. Finally, Ryall *et al.* simply states that the "quantity of each serogroup polysaccharide present in the multivalent formulation was determined by component saccharide analysis..." (paragraph [0066], line 1), but does not provide any information regarding the extent of the analysis or methods involved. One important difference between the art cited by the Examiner and the present claims is the lack of a step (e). The lack of this step is quite significant given that there is no recognition in the references of the difficulties associated with analyzing the composition of claim 1, and no teaching, suggestion, or motivation to combine references to arrive at the process of claim 1.

To address this deficiency, the Examiner states "it would have been prima facie obvious to analyze and compare the monosaccharides unique to each serogroup i.e. sialic acid for serogroup C, galactose for serogroup W135 and glucose for serogroup Y in order to determine the stability and integrity of capsular saccharide of each serotype of the vaccine."(*Id.*). Applicants respectfully assert that this is a conclusory statement, for which the Examiner has not provided support (MPEP 2142). The Examiner's conclusion is dependent upon a person of skill in the art having an appreciation and understanding of the problems associated with analyzing the composition of claim 1. However, as explained above, none of the cited references recognize the difficulties associated with obtaining an accurate analysis of the composition of claim 1.

Moreover, the Examiner's above statement highlights the exact difficulty in analyzing the composition of claim 1. Contrary to the Examiner's assertion, the content of serogroup C saccharide in the composition of claim 1 cannot be accurately determined by just analyzing sialic acid content of the composition, because sialic acid is not unique to serogroup C saccharides – it also occurs in saccharides of serogroup W135 and Y. The Examiner's obviousness analysis fails to include step (e) as presently claimed. Thus, any attempt to analyze the content of serogroup C saccharide in the composition of claim 1 by simply determining the sialic acid content of the composition will result in an overinflated calculation of the amount of serogroup C saccharide

present, because sialic acids are released from the saccharides of not only serogroup C, but also serogroups W135 and Y.

Accordingly, Applicants respectfully assert that for at least these reasons, it would not have been obvious for one having skill in the art to combine prior art references to arrive at the claimed invention.

If the Examiner maintains the rejection, Applicants respectfully request that the Examiner assess whether these differences, such as step (e) of the pending claims, would have been obvious to one of ordinary skill in the art as of the effective date in accordance with the MPEP and existing case law. The conclusory statements provided by the Examiner have not been sufficient to meet the required standards. The MPEP Section 2141(III) provides helpful guidance for this analysis:

> The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the ***reason(s)*** why the claimed invention would have been obvious. The Supreme Court in KSR noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. The Court quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006), stated that "'[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, ***there must be some articulated reasoning with some rational underpinning*** to support the legal conclusion of obviousness.'" *KSR*, 550 U.S. at ___, 82 USPQ2d at 1396. (*emphasis added*)

As discussed above, the Examiner has not cited to any portion of any of the cited references that would give one of skill in the art a reason to practice the presently claimed invention, including step (e) among others. By contrast, as indicated on page 1, line 30 through page 2, line 2, the inventors have identified the difficulties in analyzing the complex mixtures that include saccharides from serogroup C in the presence of saccharides from serogroups W and/or Y. Thus, the inventors identified a reason that the Examiner has not demonstrated as being appreciated in the art.

Applicants therefore respectfully request that the Examiner withdraw the rejections of claims 1-11 and 19-21.

III. Claim Rejections Under 35 USC §103 – Ryall in view of Ho

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ryall *et al.* WO 02/058737 8/1/02, in view of Ho *et al.* Vaccine 19 (2001) 716-725.

Applicants have canceled claim 12, thus rendering the rejection moot.

IV. Claim Rejections Under 35 USC §103 – Ryall

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ryall *et al.* WO 02/058737 8/1/02.

Applicants respectfully traverse the rejection and its supporting remarks. As amended, claim 13 recites performing the process of claim 1. Applicants respectfully assert that claim 13 is not obvious at least for the reasons provided above for claims 1-11 and 19-21.

Accordingly, Applicants respectfully request that the Examiner withdraw the rejection of claim 13.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing **Docket No. 223002119000**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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